Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Valaciclovir Bluefish is and what it is used for
2. Before you take Valaciclovir Bluefish
3. How to take Valaciclovir Bluefish
4. Possible side effects
5. How to store Valaciclovir Bluefish
6. Further information

1. What Valaciclovir Bluefish is and what it is used for

Valaciclovir Bluefish belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV). Valaciclovir Bluefish can be used to:
- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old).
- It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years of old)
- infections in the eye

2. Before you take Valaciclovir Bluefish

DO NOT take Valaciclovir Bluefish
- if you are allergic (hypersensitive) to Valaciclovir Bluefish or aciclovir or any of the other ingredients (listed in section 6).
- Don’t take Valaciclovir Bluefish if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir.

Take special care with Valaciclovir Bluefish
Check with your doctor or pharmacist before taking Valaciclovir Bluefish if:
- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valaciclovir Bluefish.

Prevent passing genital herpes on to others
If you are taking Valaciclovir Bluefish to treat or prevent genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.
Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valtrex for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding
Valaciclovir Bluefish is not usually recommended for use during pregnancy. If you are pregnant, or think you could be, or if you are planning to become pregnant, don’t take Valaciclovir Bluefish without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir Bluefish while you're pregnant or breastfeeding.

Driving and using machines
Valaciclovir Bluefish can cause side effects that affect your ability to drive. Don’t drive or use machines unless you are sure you’re not affected.

3. How to take Valaciclovir Bluefish

Always take Valaciclovir Bluefish exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Valaciclovir Bluefish for you. Your doctor will discuss this with you.

Treatment of shingles
- The usual dose is 1000 mg (one 1000 mg tablet) three times a day
- You should take Valaciclovir Bluefish for seven days.

Treatment of cold sores
- The usual dose is 2000 mg (two 1000 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose
- You should take Valaciclovir Bluefish for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes
- The usual dose is 500 mg (1/2 tablet) twice a day.
- For the first infection you should take Valaciclovir Bluefish for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them
- The usual dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking 250 mg twice a day.
- You should take Valaciclovir Bluefish until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)
- The usual dose is 2000 mg (two 1000 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valaciclovir Bluefish as soon as possible after your surgery.
- You should take Valaciclovir Bluefish for around 90 days after your surgery, until your doctor tells you to stop.

Your doctor may adjust the dose of Valaciclovir Bluefish if:
- you are over 65 years of age
• you have a weak immune system
• you have kidney problems.
→ Talk to your doctor before taking Valaciclovir Bluefish if any of the above apply.

Taking this medicine
• Take this medicine by mouth.
• Swallow the tablets whole with a drink of water.
• Take Valaciclovir Bluefish at the same time each day.
• Take Valaciclovir Bluefish according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems
It is very important while you are taking Valaciclovir Bluefish that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Valaciclovir Bluefish than you should
Valaciclovir Bluefish is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy. Talk to your doctor or pharmacist if you take too much Valaciclovir. Take the medicine pack with you.

If you forget to take Valaciclovir Bluefish
• If you forget to take Valaciclovir Bluefish, take it as soon as you remember. However, it is nearly time for your next dose, skip the missed dose.
• Do not take a double dose to make up for a forgotten dose.

4. Possible side effects
Like all medicines, Valaciclovir Bluefish can cause side effects in some people. The following side effects may happen with this medicine.

Conditions you need to look out for
• severe allergic reactions (anaphylaxis). These are rare in people taking Valaciclovir. Rapid development of symptoms including:
  - flushing, itchy skin rash
  - swelling of the lips, face, neck and throat, causing difficulty in breathing (angiodema)
  - fall in blood pressure leading to collapse.
→ If you have an allergic reaction, stop taking Valaciclovir Bluefish and see a doctor straight away.

Very Common (affects more than 1 in 10 people):
• headache

Common (affects up to 1 in 10 people)
• feeling sick
• dizziness
• vomiting
• diarrhoea
• skin reaction after exposure to sunlight (photosensitivity).
• rash

Uncommon (affects up to 1 in 100 people)
• feeling confused
• seeing or hearing things that aren’t there (hallucinations)
• feeling very drowsy
• tremors
feeling agitated

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir a day. They usually get better when Valaciclovir treatment is stopped or the dose reduced.

**Other uncommon side effects:**
- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)

**Uncommon side effects that may show up in blood tests:**
- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

**Rare** (affects up to 1 in 1,000 people)
- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir a day. They usually get better when Valaciclovir treatment is stopped or the dose reduced.

**Other rare side effects:**
- kidney problems where you pass little or no urine.

**5. How to store Valaciclovir Bluefish**

Keep out of the reach and sight of children.

Do not use Valaciclovir Bluefish after the expiry date which is stated on the blister, bottle and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Further Information**

**What Valaciclovir Bluefish contains**
- The active substance is Valaciclovir.
  Each 1000 mg film-coated tablet contains 1000 mg of valaciclovir (as valaciclovirhydrochloride).

  - The other ingredients are microcrystalline cellulose, crospovidone (Type A), povidone K90, magnesium stearate, Opadry blue 13B5057 (hypromellose, indigo carmine aluminium lake (E132), titanium dioxide (E171), macrogol 400, polysorbate).

**What Valaciclovir Bluefish looks like and contents of the pack**

Film-coated tablet.
Valaciclovir Bluefish 1000 mg film-coated tablets
Blue, film coated, capsule shaped tablets with partial scorebar on both sides containing ‘F’ on one side and ‘8’ and ‘3’ on the other side.
The tablet can be divided into equal halves.

Valaciclovir Bluefish film-coated tablets are available in clear PVC/PVdC Aluminium foil blister pack or in HDPE bottle pack.

**Blister pack:**
- **1000 mg:** 5, 10, 14, 21, 24, 30, 42, 50 and 90 tablets

**Bottle pack:**
- **1000 mg:** 30 and 500 tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
To be completed nationally

**Manufacturer**
To be completed nationally

This medicinal product is authorised in the Member States of the EEA under the following names:
To be completed nationally

**This leaflet was last approved in**
10 April 2015